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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,348	11/01/2003	Michael O. Madsen	P-11706.00US	9656
54228	7590	09/13/2006	EXAMINER	
IPLM GROUP, P.A. POST OFFICE BOX 18455 MINNEAPOLIS, MN 55418			SZMAL, BRIAN SCOTT	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 09/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/698,348

Applicant(s)

MADSEN, MICHAEL O.

Examiner

Brian Szmaj

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-18 is/are allowed.
- 6) ☒ Claim(s) 19-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Claim Objections

1. Claims 19 and 24 are objected to because of the following informalities:

In lines 15-16 and 14-15 respectively, "said vacuum source operating in conjunction with said vacuum source" renders the claim indefinite. It appears the phrase should read as "said structure ~~vacuum source~~ operating in conjunction with said vacuum source". Furthermore, in lines 18 and 17, respectively, "said baseline" lacks antecedent basis.

In Claim 24, line 19, "said lower esophageal sphincter" lacks antecedent basis. Appropriate correction is required.

2. Claims 20 and 25 are objected to because of the following informalities: Both claims are objected to due to the disclosure of "a baseline" which conflicts with the previously disclosed "baseline" in Claims 19 and 24, as well as "said pulling back step" which lacks antecedent basis in both claims. Appropriate correction is required.

3. Claims 21 and 26 are objected to because of the following informalities: The claims are claiming a method step within an apparatus claim. Appropriate correction is required.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. Claims 19-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kilcoyne et al (6,285,897 B1), Silverstein et al (5,247,938), Higuma et al (6,464,708 B1), in view of Sugrue et al (5,433,216).

Kilcoyne et al disclose a remote physiological monitoring system, and further disclose a device suitable for placing a monitoring device at the esophageal location in the patient, the device having a lumen and a distal end capable of being passed through the esophagus and the lower esophageal sphincter into the stomach; a means for measuring pressure within the esophagus; anchoring a capsule to the esophageal wall. See Column 5, lines 27-30; Column 7, lines 19-30; and Column 8, lines 14-23.

Kilcoyne et al however fail to disclose the exact means for measuring the pressure within the esophagus.

Silverstein et al disclose a means for determining the motility of a region in a human body and further disclose a source of gas having a constant pressure operatively coupled to the proximate end of the lumen; a pressure measurement means for measuring a lumen pressure of the gas in the lumen; a vacuum source; and the gas comprises air. See Column 3, lines 20-25 and 53-55.

Kilcoyne et al and Silverstein et al however fail to disclose the means for placing a device on the esophageal wall.

Higuma et al discloses a ligation device and further discloses a structure operatively coupled with the lumen of the device to the vacuum source for anchoring a structure to the wall of the esophagus. See Figures 34-36.

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Kilcoyne et al, Silverstein et al and Higuma et al however fail to disclose the location of the upper boundary of the lower esophageal sphincter using the pressure measurements.

Sugrue et al disclose a pressure measurement apparatus and further disclose the distal end of the device may be removed from the patient while noting an increase in the lumen pressure relative to the baseline and subsequently noting a decrease in the lumen pressure thereby identifying an upper boundary of the lower esophageal sphincter upon the decrease; and a means for determining the baseline before withdrawing the device. See Column 13, lines 58-68; Column 14, lines 10-13; Column 16, lines 5-10 and 49-68; Column 18, lines 65-67; and Column 34, lines 66-68.

While Kilcoyne et al, Silverstein et al, and Higuma et al disclose means for measuring a pressure within the esophagus and anchoring a device within the esophagus, and Sugrue et al disclose a means for identifying regions within the esophagus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Kilcoyne et al, Silverstein et al and Higuma et al to include the use of identifying a specific region within the esophagus using pressure measurements, as per the teachings of Sugrue et al, since it would provide a means of placing a device at a specific location within the esophagus.

6. Claims 21, 22, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kilcoyne et al (6,285,897 B1), Silverstein et al (5,247,938), Higuma et al (6,464,708 B1) and Sugrue et al (5,433,216) as applied to claims 19 and 24 above, and further in view of Bombeck, IV (4,981,470).

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Kilcoyne et al (6,285,897 B1), Silverstein et al (5,247,938), Higuma et al (6,464,708 B1) and Sugrue et al (5,433,216), as discussed above, disclose a means of monitoring pressure within the esophagus and placing a device at a location within the esophagus, but fail to disclose measuring a predetermined distance from the upper boundary of lower esophageal sphincter or restriction; the esophageal location is a predetermined distance above the upper boundary of the lower esophageal sphincter or restriction. Bombeck, IV disclose an esophageal catheter and further disclose measuring a predetermined distance from the upper boundary of lower esophageal sphincter or restriction; the esophageal location is a predetermined distance above the upper boundary of the lower esophageal sphincter or restriction. See Column 4, lines 38-50. Since Kilcoyne et al, Silverstein et al, Higuma et al and Sugrue et al disclose a means for measuring the esophageal pressure and placing a device at a location within the esophagus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Kilcoyne et al, Silverstein et al, Higuma et al and Sugrue et al to include the means of measuring the distance from the sphincter or restriction, as per the teachings of Bombeck, IV since it would provide a means of precisely locating and placing a monitoring device on the esophageal wall.

Allowable Subject Matter

7. The following is a statement of reasons for the indication of allowable subject matter: Claims 1-18 are allowable since Claims 1 and 10 contain "establishing the

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esophageal location relative to the upper boundary of the lower esophageal sphincter; and anchoring a capsule to the esophagus with the catheter.

Response to Arguments

8. Applicant's arguments with respect to claims 19-28 have been considered but are moot in view of the new ground(s) of rejection.

9. Applicant's arguments, filed June 22, 2006, with respect to Claims 1-18 have been fully considered and are persuasive. The rejection of Claims 1-18 has been withdrawn.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

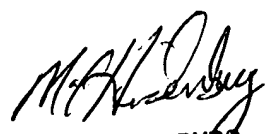
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmalec whose telephone number is (571) 272-4733. The examiner can normally be reached on Monday-Thursday, with Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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